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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,542	02/12/2004	Unchalee Kositprapa	141-446	5119

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EXAMINER	
WEDDINGTON, KEVIN E	
ART UNIT	PAPER NUMBER
1614	
MAIL DATE	DELIVERY MODE
08/06/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/777,542	KOSITPRAPA ET AL.	
	Examiner	Art Unit	
	KEVIN WEDDINGTON	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,15,17-20 and 23-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,15,17-20 and 23-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6-4-09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 1-4, 15, 17-20 and 23-26 are presented for examination.

Applicants' amendment and response filed march 31, 2009; and the information disclosure statement filed June 4, 2009 have been received and entered.

Accordingly, the rejection made under 35 USC 112, first paragraph (New Matter) as set forth in the previous Office action dated February 2, 2009 at pages 2-4 is hereby withdrawn because the applicants deleted the phrase "consisting essentially of".

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 15, 17-20 and 23-26 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 47-50 and 55-63 of copending Application No. 11/093,742. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present application teaches a pharmaceutical dosage form with a controlled release core

comprising only metformin and an immediate release layer of pioglitazone. The thiazolidinedione related compounds or impurities are not more than 0.6%, 0.5%, 0.2%, or 0.10% as determined by HPLC; and the copending application teaches a pharmaceutical dosage with the same active agents wherein pioglitazone layer has a low viscosity water soluble binder added.

Obviously, one skilled in the art can added this binder to the present application as achieve the same results in the absence of evidence to the contrary.

Claims 1-4, 15, 17-20 and 23-26 are not allowed.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 15, 17-20 and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adjei et al. (6,403,121 B1) in view of Menon et al., The American Journal of Gastroenterology, Vol. 96, No. 5, pps. 1631-1634 (2001).

Adjei et al. teach a core formulation comprising a first layer comprising pioglitazone, which covers at least a portion of a core comprising the biguanide, metformin (i.e. glucophage). Note the reference also teaches the metformin in the core is present in an amount of 10-97.5 wt.% of the total core formulation (see column 2, lines 59-62). Also note column 5, lines 45-59 teaches the excipents, such as binders, disintegrating agents, lubricants, glidants, and sweetening agents.

The instant invention differs from the cited reference in that the cited reference does not teach the amount of pioglitazone impurities of not more than 0.6%, 0.5%, 0.25%, 0.20% and 0.10% as determined by high performance liquid chromatography (HPLC). However, the secondary reference, Menon et al., teaches a pioglitazone related compound or impurity, troglitazone. According to Menon et al., troglitazone was

approved for the treatment of diabetes mellitus; but hepatic abnormalities were reported in up to 1.9% of patients receiving the drug (abstract).

Therefore, it would have been obvious to an artisan of ordinary skill at the time the invention was made to maintain low levels of pioglitazone related compounds or impurities in the dosage forms of Adjei et al. comprising pioglitazone. One would have been motivated to do so because of the side effects, such as severe hepatoxicity, that results from these related compounds or impurities. Furthermore, since Adjei et al. is silent regarding pioglitazone impurities and the Examiner has no access to laboratory equipment, burden is put on applicants to prove that the reference teaches otherwise. When the reference discloses all the limitations of a claim except a property or function and the Examiner cannot determine whether or not the reference inherently possesses properties which anticipates or render obvious the claimed invention, the Examiner can shift the burden of proof to applicants as in In re Fitzgerald, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

Regarding the release profiles of pioglitazone and the Tmax of pioglitazone and metformin in claims 25 and 26, these limitations are intended uses for the composition. Because dissolution properties do not materially impact the structure of the composition itself, they are not given any patentable weight, Since the prior art teaches the core structure of the formulation (metformin in the core and pioglitazone in an outer layer) the formulation is capable of having the instantly claimed dissolution characteristics when tested using Apparatus I depending on the amount of drug and low viscosity water soluble binder added to the formulation. Further, one skilled in the art would have been

motivated to alter the dissolution characteristics of a drug formulation depending on the needs of a particular patient population.

Claims 1-4, 15, 17-20 and 23-26 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KEVIN WEDDINGTON whose telephone number is (571)272-0587. The examiner can normally be reached on 12:30 pm - 9:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KEVIN WEDDINGTON
Primary Examiner
Art Unit 1614

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